PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of	Docket No: Q84102
Shunji HAYASHI, et al.	
Appln. No.: 10/510,497	Group Art Unit: 1794
Confirmation No.: 1554	Examiner: Hamid R. BADR
Filed: October 7, 2004	

For: CHEESE CAPABLE OF DISINFECTING HELICOBACTER PYLORI

DECLARATION UNDER 37 C.F.R. § 1.132

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Mitsuro MATSUO, hereby declare and state:

THAT I am a citizen of Japan;

THAT I have received the degree of Master of Agriculture in 1989 from Kyoto University in Kyoto, Japan;

THAT I have been employed by Meiji Dairies Corporation since April in 1989, where I hold a position as Manager in Cheese Section in Cheese and Culinary Science Department, with responsibility for studies of production of cheese;

THAT I am familiar with relevant technology of the above application.

I submit the present Declaration in support of the patentability of the invention over Gardiner et at. (1998, Development of a probiotic cheddar cheese containing human -derived

Lactobacillus paracasei strains; hereinafter "Gardiner") in view of DE 1955833 (hereinafter "R2") and Kimura et al. (EP 1 112 692 A1, hereinafter "Kimura").

(1) "timing of addition of yeast extract"

The process claimed in the present invention requires adding an yeast extract to the raw milk at the same time or after adding the lactic acid bacteria starter to the raw milk in step (1), and before formation of the curd in step (2).

When cheese is produced by adding yeast extract to milk component before formation of curd, *L. gasseri* increases during one month of preservation and keeps a high bacterial count. On the other hand, when cheese is produced without adding yeast extract, *L. gasseri* dose not increase during preservation of cheese and the bacterial count decreases with lapse of time of preservation.

In addition, it is knowledge in the art that each *Lactobacillus* strains has different growth rate and survival rate under the same acid condition. It is not reasonable to assume all *Lactobacillus* strains are expected to have same growth rate and survival rate overtime when incorporated into cheese, and it is not reasonable to assume that *L. paracasei* and *Lactobacillus gasseri* strains are interchangeable.

(2) "incubation of the curd"

Further, the process claimed in the present invention requires that the incubation of the curd is carried out without cooling the curd after molding and pressing.

The instant specification discloses at page 14, second paragraph, that the survival ratio of

L. gasseri in the natural cheese can be improved by incubating the curd after the molding and pressing (i.e., formation of the pressed pieces of curd). The incubation is preferably carried out, for example, without cooling immediately after the molding and pressing. Furthermore, the incubation is carried out at 20 to 35°C for 16 to 26 hours, preferably at 22 to 28°C for 19 to 24 hours.

According to the method defined in the present claim 6, the "incubation" of the curd is conducted on the curd obtained after removing whey, molding and pressing, and forming pieces of the curd kept at 20 to 35 °C for 16 to 26 hours.

In contrast, in Gardiner, the cheese is kept for one night outside of a room during pressing and molding in process of removing whey in cheese production, which is different from the "incubation" of the present application.

I, based on my experience and knowledge in the art, understand that increasing the viable count of a certain microorganism to a target level by controlling the temperature and time of incubation of a curd that comprises the certain microorganism is different from keeping a cheese outside of a room.

In the present application, "incubation" is carried out for increasing viable count. It is different from "aging" and "maturation" which are process in usual cheese production for improving taste and flavor by hydrolysis of protein by enzymes which are excreted from dead microorganism etc.

When curd after molding and pressing is incubated without cooling, L. gasseri increases during one month of preservation and keep high bacterial count. On the other hand, when curd

after molding and pressing is incubated with cooling, *L. gasseri* dose not increase during preservation of cheese and a decrease in the bacterial count due to elapse of time of preservation.

(3) "viable cell count overtime"

The natural cheese produced according to the process of the present application has the lactic acid bacterium belonging to *Lactobacillus gasseri* having a disinfection potency against *Helicobacter pylori*, wherein the natural cheese has a viable cell count of *Lactobacillus gasseri* in the number of 10^7 cfu/g or more when preserved at a temperature of 10°C or less for 6 months.

I, based on my experience, understand that it is difficult to keep necessary microorganisms at a desired level overtime, because microorganisms in cheese usually become dead microorganisms during process of improving taste and flavor in "aging" and "maturation" by hydrolysis of protein by enzymes which are excreted from dead microorganism. When plural microorganisms exist in cheese, the person skilled in the art cannot know which microorganism will survive. Therefore, the present invention wherein target microorganism can survive in object amount or more is novel and unobvious.

Attorney Docket No.: Q84102
U.S. Application No.: 10/510,497

I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: February 10, 2010

Mitsuro MATSUO
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